



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,889	06/15/2001	Thomas F. Haddock	ACU-10102/29	9800

7590

08/12/2002

John G. Posa
Gifford, Krass, Groh et al
Suite 400
280 N. Old Woodward Ave.
Birmingham, MI 48009

EXAMINER

MARMOR II, CHARLES ALAN

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 08/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

S.M.

Office Action Summary

Application No.	Applicant(s)	
09/882,889	HADDOCK ET AL.	
Examiner	Art Unit	
Charles A. Marmor, II	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 June 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2,3,5,6</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The filewrapper for the instant application indicates that five Information Disclosure Statements have been filed. The filewrapper further indicates that two of these Information Disclosure Statements were filed on May 9, 2002. The application file only contains four Information Disclosure Statements. Only one of said four Information Disclosure Statements bears the date of May 9, 2002. The examiner would like to inquire whether the fifth IDS is missing from the file, or if a clerical error has been made by the Office.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character “422” has been used to designate both a “rim” as described at page 17, line 10 and a “cable” as described at page 17, line 14. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: “102” and “104” as illustrated in Fig. 1A and Fig. 1B; “310” and “312” as illustrated in Fig. 3C; “406” as illustrated in Fig. 4A; and “442” as illustrated in Fig. 4D. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are

Art Unit: 3736

required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

4. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

5. The abstract of the disclosure is objected to because it too long and exceeds the 150 word limit. Correction is required. See MPEP § 608.01(b).

6. The disclosure is objected to because of the following informalities:

- a. On page 8, line 9, it is unclear what "O.D." represents.
- b. On page 13, line 20, it is unclear what "O.D." represents.
- c. On page 16, line 11 and 12, "materials 302 forming the arms" apparently should read
--materials forming the fingers 302--.
- d. On page 16, line 19, --illustrate-- apparently should be inserted before "preferred".
- e. On page 19, line 12, "are or" apparently should be deleted.

Appropriate correction is required.

7. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

8. Claim 9 is objected to because of the following informalities: in line 1, --is-- apparently should be inserted before "conically". Appropriate correction is required.

9. Claim 14 is objected to because of the following informalities:

- a. In line 1, --the-- apparently should be inserted before "temperature".
- b. In line 2, "grove extend" apparently should read --groove extends--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, the preamble of the claim is indefinite. It is unclear what

Art Unit: 3736

temperatures the system is intended to measure. The preamble recites that the system is for measuring the temperature of an arterial wall; however, arterial walls are not mentioned again in the bodies of claims 1-15. Furthermore, the preamble recites that the system is for measuring the temperature of other vessels; however, it is not clear whether the temperature is measured for the entire vessel or only a wall thereof.

Claim 1 recites the limitation "the vessel wall" in line 11. There is insufficient antecedent basis for this limitation in the claim. There is no vessel wall recited in the claim prior to this recitation. This limitation is also recited in line 2 of claim 7.

Claim 3 recites the limitation "the effects" in line 2. There is insufficient antecedent basis for this limitation in the claim. There are no effects recited in the claim prior to this recitation.

Claim 4 recites the limitation "the effects" in line 3. There is insufficient antecedent basis for this limitation in the claim. There are no effects recited in the claim prior to this recitation.

Further regarding claim 4, it is from the claim language what cross section of the presentation elements is being claimed and in what manner the sensors are disposed asymmetrically relative to the cross section.

Claim 5 recites the limitation "the expanded condition" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim. There is no expanded condition recited in the claim prior to this recitation. It is unclear if the limitation "the expanded condition" is the same as the limitation "the expanded position" recited in line 10 of claim 1.

Claim 9 recites the limitation "the area" in line 1. There is insufficient antecedent

basis for this limitation in the claim. There is no area where the plunger causes the fingers to spread recited in the claim prior to this recitation.

Claim 11 recites the limitation "the presentation system" in line 2. There is insufficient antecedent basis for this limitation in the claim. There is no presentation system recited in the claim prior to this recitation.

Further regarding claim 11, the addition of the word "like" to an otherwise definite expression extends the scope of the expression so as to render it indefinite.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-6, 8 and 11-15 are rejected under 35 U.S.C. 102(a) as being anticipated by Naghavi et al. Naghavi et al. teach a system for sensing the temperature of an arterial wall or other vessel, including an elongated catheter having a distal end with a temperature sensing tip and a proximal end including a manually operated expansion control. The temperature sensing tip includes one or more presentation elements such that each element has a temperature sensor supported thereon. The presentation elements are physically coupled to the manually operated expansion control such that operation of the control causes the elements and temperature sensors to move between a retracted position, enabling the temperature sensing tip to be positioned in a

section of the vessel to be measured, and an expanded position, where the sensors are in contact or immediately proximate to the vessel wall. The system further includes a data unit operative to receive signals from the temperature sensors and display information indicative of vessel wall temperature as sensed by the sensors. The temperature sensors are thermistors. The presentation elements are thermally insulative so that the sensors are isolated from the effects of blood flow or other ambient conditions. The presentation elements have a cross section, and the sensors are disposed asymmetrically relative to the cross section so that the sensors are isolated from the effects of blood flow or other temperature gradients. The presentation elements are further configured such that blood may continue to flow around the elements when the elements are in the expanded condition. The temperature sensing tip features a plurality of longitudinal slices such that the presentation system assumes a basket-like structure which flares out in response to the manually operated expansion control. The system further includes at least one thermal sensor to measure a non-wall temperature. The presentation elements include an outer longitudinal groove into which the temperature sensors are embedded. The temperature sensors are hardwired to the data unit, and the groove extends the length of the catheter to receive the wires. The catheter is disposable.

14. Claims 1, 4-6, 8 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown. Brown teaches a system for sensing the temperature of an arterial wall or other vessel (Fig. 5A-B), including an elongated catheter **24** having a distal end with a temperature sensing tip and a proximal end including a manually operated expansion control. The temperature sensing tip includes one or more presentation elements such that each element has a temperature

Art Unit: 3736

sensor 18 supported thereon. The presentation elements are physically coupled to the manually operated expansion control 26 such that operation of the control causes the elements and temperature sensors to move between a retracted position, enabling the temperature sensing tip to be positioned in a section of the vessel to be measured, and an expanded position, where the sensors are in contact or immediately proximate to the vessel wall. The system further includes a data unit 22,40,42,44 operative to receive signals from the temperature sensors and display information indicative of vessel wall temperature as sensed by the sensors. The presentation elements have a cross section, and the sensors are disposed asymmetrically relative to the cross section so that the sensors are isolated from the effects of blood flow or other temperature gradients. The presentation elements are further configured such that blood may continue to flow around the elements when the elements are in the expanded condition. The presentation elements are fingers which expand outwardly in response to the manually operated expansion control. The fingers surround a central plunger 66 coupled to the manually operated expansion control, such that pulling on the plunger causes the fingers to expand outwardly. The plunger is conically shaped in the area 64 where the plunger causes the fingers to spread.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3736

16. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Waldman et al. ('880) in view of Brown.

Waldman et al. ('880) teach an endocardial electrical mapping catheter. The catheter **10** has a distal end with a sensing tip **16** and a proximal end including a manually operated expansion control **32a-h**. The sensing tip includes one or more presentation elements **18a-h** such that each element has a sensor **20** supported thereon. The presentation elements are physically coupled to the manually operated expansion control such that operation of the control causes the elements and sensors to move between a retracted position, enabling the sensing tip to be positioned in a section of the vessel to be measured, and an expanded position, where the sensors are in contact or immediately proximate to the vessel wall. The system further includes a data unit operative to receive signals from the sensors and display information. The presentation elements are cantilevered fingers that provide a relatively constant and uniform force against the organ wall. Waldman et al. ('880) teach all of the limitations of the claims except that sensors are temperature sensors.

Brown, as described hereinabove, teaches a device for locating inflamed plaque in an artery. The device includes an elongated catheter having a temperature sensing tip including a plurality of presentation elements such that each presentation element includes a temperature sensor supported thereon.

It would have been obvious to one having ordinary skill in the art at the time applicant's invention was made to use temperature sensors as the sensor elements on a catheter similar to that of Waldman et al. ('880) in light of the teachings of Brown in order to obtain a thermal map of a body lumen to locate inflamed plaque in that lumen.

Allowable Subject Matter

17. Claim 10 apparently would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

18. The following is a statement of reasons for the indication of allowable subject matter:

No prior art of record teaches or fairly suggests a thermal sensing catheter as claimed in claim 9 where the fingers include an inner lip configured to engage with the conical plunger to protect against over-spreading of the fingers.

Conclusion

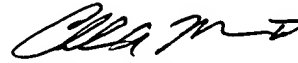
19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Zikorus et al. teach an expandable vein ligator catheter having a plurality of electrodes, cantilevered presentation elements and a temperature sensor.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on (703) 308-2582. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 308-0758 for After Final communications.

Art Unit: 3736

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Charles A. Marmor, II
Examiner
Art Unit 3736

CAM
August 7, 2002